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**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| **AMGEN INC.,**<br><br>**Plaintiff,**<br><br>**v.**<br><br>**APOTEX INC.,**<br><br>**Defendant.** | **Civil Action No.** 22-cv-3827<br><br>**(Filed Electronically)** |

# COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Amgen Inc. ("Amgen" or "Plaintiff"), by its undersigned attorneys, brings this action against Defendant Apotex Inc. ("Apotex" or "Defendant"), and hereby alleges as follows:

## NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. § 271. This action relates

to Abbreviated New Drug Application ("ANDA") No. 217258 (hereinafter, "Apotex's ANDA"), filed by and for the benefit of Apotex with the United States Food and Drug Administration ("FDA"). Through Apotex's ANDA, Apotex seeks approval to market generic versions of Amgen's OTEZLA® (apremilast) 10 mg, 20 mg, and 30 mg tablets (hereinafter, "Apotex's Infringing ANDA Products"), prior to the expiration of Amgen's United States Patent Nos. 7,427,638 ("the '638 Patent"), 9,872,854 ("the '854 Patent"), and 10,092,541 ("the '541 Patent") (collectively, "the Patents-in-Suit").

## THE PARTIES

2. Plaintiff Amgen is a biopharmaceutical company that discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry. Amgen is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799.

3. On information and belief, Defendant Apotex Inc. is a Canadian corporation having a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

## JURISDICTION AND VENUE

4. This is a civil action for patent infringement arising under the patent laws of the United States, including 35 U.S.C. § 271, for infringement of the Patents-in-Suit.

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

6. This Court has personal jurisdiction over Apotex because, *inter alia*, on information and belief, Apotex has continuous and systematic contacts with the State of New Jersey, regularly conducts business in the State of New Jersey, either directly or through one or more wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing

business in the State of New Jersey, and intends to sell Apotex's Infringing ANDA Products in the State of New Jersey upon approval of Apotex's ANDA.

7. On information and belief, Apotex is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within the State of New Jersey, through its own actions and through the actions of its agents and subsidiaries, from which Apotex derives a substantial portion of its revenue.

8. On information and belief, Apotex, through its own actions and through the actions of its agents and subsidiaries, has engaged in the research and development, and the preparation and filing, of Apotex's ANDA, continues to engage in seeking FDA approval of this ANDA, intends to engage in the commercial manufacture, marketing, offer for sale, sale, or importation of Apotex's Infringing ANDA Products throughout the United States, including within the State of New Jersey, and stands to benefit from the approval of Apotex's ANDA.

9. On information and belief, Apotex, through its own actions and through the actions of its agents and subsidiaries, prepared and submitted Apotex's ANDA with a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

10. On information and belief, following FDA approval of Apotex's ANDA, Apotex intends to market, offer to sell, sell, or distribute Apotex's Infringing ANDA Products throughout the United States and within the State of New Jersey, that will, as explained below, infringe upon Amgen's rights in the Patents-in-Suit protecting its OTEZLA® products. On information and belief, following FDA approval of Apotex's ANDA, Apotex knows and intends that Apotex's Infringing ANDA Products will be marketed, used, distributed, offered for sale, or sold in the United States and within the State of New Jersey.

11. Apotex has consented to personal jurisdiction in this Court in numerous recent actions arising out of its ANDA filings and has filed counterclaims in such cases. *See, e.g.*, *Supernus Pharms., Inc. v. Apotex Inc. et al.*, No. 20-cv-07870 (D.N.J. filed June 26, 2020); *Boehringer Ingelheim Pharms., Inc. et al. v. Apotex Inc. et al.*, No. 18-cv-11350 (D.N.J. filed July 3, 2018); *Pantheon Softgels Inc. et al. v. Apotex Inc. et al.*, No. 17-cv-13819 (D.N.J. filed Dec. 29, 2017) ; *Merck Sharp & Dohme Corp. v. Apotex Inc. et al.*, No. 17-cv-5399 (D.N.J. filed July 24, 2017); *Dexicel Pharma Techs. Ltd. et al. v. Apotex Corp. et al.*, No. 17-cv-2423 (D.N.J. Apr. 7, 2017). Apotex has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

12. This Court also has personal jurisdiction over Apotex at least because, *inter alia*, (a) Apotex has filed an ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Apotex's Infringing ANDA Products in the United States, including in the State of New Jersey; (b) Apotex, through its own actions and through the actions of its agents and subsidiaries, will market, distribute, offer to sell, or sell Apotex's Infringing ANDA Products in the United States, including in the State of New Jersey and to residents of this Judicial District, upon approval of Apotex's ANDA, and will derive substantial revenue from the use or consumption of Apotex's Infringing ANDA Products in the State of New Jersey; and (c) Apotex has purposefully availed itself of the privilege of doing business in the State of New Jersey by placing goods into the stream of commerce for distribution throughout the United States and within the State of New Jersey, and/or by selling, directly or through its agents, pharmaceutical products in the State of New Jersey. On information and belief, if Apotex's ANDA is approved, Apotex's Infringing ANDA Products charged with infringing the Patents-in-Suit would, *inter alia*, be marketed, distributed, offered for sale, or sold in the State of New Jersey, prescribed by

physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

13. This Court also has personal jurisdiction over Apotex because Apotex has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Amgen, a corporation that manufactures OTEZLA® drug products for sale and use throughout the United States, including in this Judicial District. On information and belief, Apotex filed Apotex's ANDA with a Paragraph IV Certification, which was purposefully directed to the State of New Jersey, where Amgen sells OTEZLA® drug products. As a result, the consequences of Apotex's actions were, and will be, suffered in the State of New Jersey. Apotex knew or should have known that the consequences of its actions were, and will be, suffered in the State of New Jersey. At the time Apotex sent notice of the Paragraph IV Certification, it was reasonably foreseeable that Apotex would be sued within 45 days in this Judicial District. On information and belief, Apotex's actions will injure Amgen by displacing at least some, if not all, of Amgen's sales of OTEZLA® drug products in this Judicial District, as well as resulting in price erosion and loss of goodwill with the purchasers and distributors of OTEZLA® drug products in this Judicial District.

14. Apotex has represented that it will not object to personal jurisdiction in New Jersey for purposes of this matter only.

15. In the alternative, this Court has personal jurisdiction over Apotex because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Amgen's claims arise under federal law; (b) Apotex is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Apotex has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing,

importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Apotex satisfies due process.

16. On information and belief, Apotex has also engaged in substantial, systematic, and continuous contacts with New Jersey that satisfy due process and confer personal jurisdiction over Apotex in New Jersey.

17. At least because, on information and belief, Apotex is a foreign company, venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b). Apotex has represented that it will not object that venue is proper in New Jersey for purposes of this matter only.

## AMGEN'S PATENTS AND APPROVED OTEZLA® DRUG PRODUCTS

18. Amgen makes and sells OTEZLA® (apremilast) 10 mg, 20 mg, and 30 mg tablets (collectively, "OTEZLA®") for oral use to treat adult patients with active psoriatic arthritis (Indication 1.1), adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy (Indication 1.2), and adult patients with oral ulcers associated with Behçet's Disease (Indication 1.3). The active ingredient in OTEZLA® is apremilast. A true and correct copy of the prescribing information for Amgen's OTEZLA® is attached as Exhibit A.

19. Amgen holds New Drug Application ("NDA") No. 205437, under which FDA first approved the marketing of OTEZLA® on March 21, 2014.

20. OTEZLA® and one or more of its approved uses are covered by claims of the Patents-in-Suit.

21. The Patents-in-Suit are listed in *Approved Drug Products With Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "*Orange Book*") in connection with NDA No. 205437.

22. OTEZLA® is the first approved pharmaceutical product to contain apremilast. In recognition of this, the FDA granted OTEZLA® five years of regulatory exclusivity for a new chemical entity, which expired on March 21, 2019, pursuant to 21 C.F.R. § 314.108.

23. Celgene Corporation ("Celgene") previously held NDA No. 205437 and was the assignee of the Patents-in-Suit.

24. On January 3, 2019, Celgene announced that it had entered into a merger agreement under which Bristol-Myers Squibb Company ("BMS") would acquire Celgene.

25. On June 24, 2019, BMS announced that it was planning to divest OTEZLA® in light of the proposed merger transaction.

26. Celgene and Amgen entered into an asset purchase agreement for OTEZLA® on August 25, 2019 that included, among other things, NDA No. 205437, the regulatory approvals associated with OTEZLA®, and all patents listed in the *Orange Book* for NDA No. 205437, including the Patents-in-Suit.

27. Effective November 21, 2019, Celgene's entire interest in and to the Patents-in-Suit was transferred from Celgene to Amgen.

28. Amgen, as the assignee, owns the entire right, title, and interest in each of the Patents-in-Suit. Amgen has the right to enforce each of the Patents-in-Suit.

29. The '638 Patent is entitled, "(+)-2-[1-(3-Ethoxy-4-Methoxyphenyl)-2-Methylsulfonylethyl]-4-Acetylaminoisoindoline-1,3-Dione, and Methods of Synthesis and Compositions Thereof." The '638 Patent was duly and legally issued on September 23, 2008. The *Orange Book* presently shows that the '638 Patent's term ends on February 16, 2028. A true and correct copy of the '638 Patent is attached as Exhibit B.

30. The ’854 Patent is entitled, “Methods For the Treatment of Psoriatic Arthritis Using Apremilast.” The ’854 Patent was duly and legally issued on January 23, 2018. The *Orange Book* presently shows that the ’854 Patent’s term ends on May 29, 2034. A true and correct copy of the ’854 Patent is attached as Exhibit C.

31. The ’541 Patent is entitled, “Methods for the Treatment of Diseases Ameliorated by PDE4 Inhibition Using Dosage Titration of Apremilast.” The ’541 Patent was duly and legally issued on October 9, 2018. The *Orange Book* presently shows that the ’541 Patent’s term ends on May 29, 2034. A true and correct copy of the ’541 Patent is attached as Exhibit D.

32. In 2018, Celgene asserted the ’638 Patent, ’854 Patent, and ’541 Patent, among other patents listed in the *Orange Book* in connection with NDA No. 205437, in this Judicial District pursuant to the Hatch-Waxman Act, against a number of entities that filed ANDAs seeking approval to market generic versions of OTEZLA® (apremilast) 10 mg, 20 mg, and 30 mg tablets. These actions were consolidated under Civil Action No. 18-11026 for discovery and case management purposes. *See Celgene Corp. v. Sandoz Inc. et al.*, No. 18-cv-11026, ECF No. 30 (D.N.J. Oct. 23, 2018); *Celgene Corp. v. Sandoz Inc. et al.*, No. 18-11026, ECF No. 174 (D.N.J. Dec. 19, 2019).

33. Amgen was substituted as Plaintiff in the consolidated actions on February 12, 2020 in light of Amgen’s acquisition of Celgene’s interest in OTEZLA®, NDA No. 205437, and regulatory approvals and intellectual property associated with OTEZLA®, including the Patents in-Suit. *Amgen Inc. v. Sandoz Inc. et al.*, No. 18-cv-11026, ECF No. 195 (D.N.J. Feb. 12, 2020).

34. Prior to trial, all Defendants against whom the ’854 Patent was asserted voluntarily settled.

35. A consolidated, nine-day trial was held before the Honorable Michael A. Shipp from June 14, 2021 through June 25, 2021. Amgen asserted five patents at trial, including the '638 Patent and '541 Patent. Specifically, Amgen asserted claims 3 and 6 of the '638 Patent and claims 2, 19, and 21 of the '541 Patent.

36. Judge Shipp issued his Opinion and Order on Final Judgment on September 20, 2021. *Amgen Inc. v. Sandoz Inc. et al.*, No. 18-cv-11026, ECF Nos. 510, 511 (D.N.J. Sept. 20, 2021). Final Judgments were entered as to Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus") and Sandoz Inc. ("Sandoz") on September 28, 2021 and October 12, 2021, respectively. *Amgen Inc. v. Sandoz Inc. et al.*, No. 18-cv-11026, ECF No. 516 (D.N.J. Sept. 28, 2021); *Amgen Inc. v. Sandoz Inc. et al.*, No. 18-cv-11026, ECF No. 525 (D.N.J. Oct. 12, 2021).

37. The '638 Patent was adjudged to be infringed by Sandoz and Zydus and not invalid. *Amgen Inc. v. Sandoz Inc. et al.*, No. 18-cv-11026, ECF No. 516 (D.N.J. Sept. 28, 2021); *Amgen Inc. v. Sandoz Inc. et al.*, No. 18-cv-11026, ECF No. 525 (D.N.J. Oct. 12, 2021).

38. Claims 2, 19, and 21 of the '541 Patent were adjudged to be invalid as obvious under 35 U.S.C. § 103. *Amgen Inc. v. Sandoz Inc. et al.*, No. 18-cv-11026, ECF No. 516 (D.N.J. Sept. 28, 2021); *Amgen Inc. v. Sandoz Inc. et al.*, No. 18-cv-11026, ECF No. 525 (D.N.J. Oct. 12, 2021).

39. Zydus appealed the Court's Final Judgment on October 27, 2021, *Amgen Inc. v. Sandoz Inc. et al.*, No. 18-cv-11026, ECF No. 526 (D.N.J. Oct. 27, 2021), and Sandoz appealed the Court's Final Judgment on November 9, 2021, *Amgen Inc. v. Sandoz Inc. et al.*, No. 18-cv-11026, ECF No. 528 (D.N.J. Nov. 9, 2021), including the Court's ruling concerning the validity and enforceability of the '638 Patent.

40. Amgen cross-appealed the Court's Final Judgment as to Zydus on October 28, 2021. *Amgen Inc. v. Sandoz Inc. et al.*, No. 18-cv-11026, ECF No. 527 (D.N.J. Oct. 28, 2021). Amgen also cross-appealed the Court's Final Judgment as to Sandoz on November 10, 2021. *Amgen Inc. v. Sandoz Inc. et al.*, No. 18-cv-11026, ECF No. 530 (D.N.J. Nov. 10, 2021). Amgen appealed both Final Judgments as to all adverse findings, holdings, rulings, determinations, conclusions, orders, opinions, decisions, and judgments leading thereto or merged or incorporated therein, including the Court's ruling concerning the validity of claims 2, 19, and 21 of the '541 Patent.

41. Zydus's appeal, Sandoz's appeal, and Amgen's cross-appeals were consolidated under Federal Circuit Appeal No. 22-1147. *Amgen Inc. v. Sandoz Inc. et al.*, No. 22-1147, ECF No. 6 (Fed. Cir. Nov. 18, 2021). The appeals are pending.

**APOTEX'S ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION**

42. On information and belief, Apotex has submitted or caused to be submitted Apotex's ANDA to FDA under 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the apremilast tablets described therein, as a purported generic version of OTEZLA®, prior to the expiration of the Patents-in-Suit.

43. On information and belief, Apotex's Infringing ANDA Products are tablets that comprise 10 mg, 20 mg, or 30 mg of apremilast as the active pharmaceutical ingredient.

44. On information and belief, FDA has not yet approved Apotex's ANDA.

45. Apotex notified Amgen that it had submitted Apotex's ANDA by letter dated May 5, 2022 and received by Amgen on May 6, 2022. ("Notice Letter"). The Notice Letter represented that Apotex had submitted Apotex's ANDA to FDA with a purported Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to obtain approval to engage in the commercial

manufacture, use, offer for sale, sale, or importation into the United States of the products described in Apotex's ANDA, before the expiration of the patents listed in the *Orange Book* for OTEZLA®. Hence, Apotex's purpose in submitting Apotex's ANDA is to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Infringing ANDA Products before the expiration of the Patents-in-Suit.

46. The Notice Letter states that the Paragraph IV Certification in Apotex's ANDA alleges that the Patents-in-Suit are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Infringing ANDA Products.

47. The Notice Letter contained a purported detailed statement of the factual and legal basis for Apotex's opinion that the Patents-in-Suit are purportedly invalid, unenforceable, or not infringed by the manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Infringing ANDA Products ("Paragraph IV Statement").

48. On information and belief, Apotex, through its own actions and through the actions of its agents and subsidiaries, has assisted with and participated in the preparation and submission of Apotex's ANDA, has provided material support to the preparation and submission of Apotex's ANDA, and intends to support the further prosecution of Apotex's ANDA.

49. On information and belief, if FDA approves Apotex's ANDA, Apotex will manufacture, offer to sell, or sell Apotex's Infringing ANDA Products within the United States, including within the State of New Jersey, or will import Apotex's Infringing ANDA Products into the United States, including New Jersey.

50. On information and belief, if FDA approves Apotex's ANDA, Apotex will actively induce or contribute to the manufacture, use, offer to sell, sale, or importation of Apotex's Infringing ANDA Products in the United States.

51. Amgen brings this action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of receipt of the Notice Letter.

**COUNT 1**
**INFRINGEMENT OF THE '638 PATENT**

52. Amgen states, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

53. On information and belief, Apotex has submitted or caused the submission of Apotex's ANDA to FDA and continues to seek FDA approval of Apotex's ANDA.

54. Apotex has infringed the '638 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Apotex's ANDA with a Paragraph IV Certification and seeking FDA approval of Apotex's ANDA prior to the expiration of the '638 Patent.

55. The '638 Patent includes claims that recite (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione; or a pharmaceutical composition or a single unit dosage form comprising (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione.

56. On information and belief, Apotex's Infringing ANDA Products contain (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione.

57. On information and belief, Apotex's Infringing ANDA Products are pharmaceutical compositions or single unit dosage forms containing (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione.

58. Apotex's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Apotex's Infringing ANDA Products would directly infringe, or would actively induce or contribute to infringement of the '638 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c). Accordingly, unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will make, use, offer for sale, or sell Apotex's Infringing ANDA Products within the United States, or will import Apotex's Infringing ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '638 Patent. *See id.*

59. On information and belief, upon FDA approval of Apotex's ANDA, Apotex, through its own actions and through the actions of its agents and subsidiaries, will market and distribute Apotex's Infringing ANDA Products to resellers, pharmacies, hospitals and other clinics, healthcare professionals, and end users of Apotex's Infringing ANDA Products. On information and belief, Apotex will also knowingly and intentionally accompany Apotex's Infringing ANDA Products with a product label and product insert that will include instructions for using or administering Apotex's Infringing ANDA Products. On information and belief, the product label and product insert accompanying Apotex's Infringing ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for OTEZLA®, attached as Exhibit A, and which, if followed, will infringe the '638 Patent. Accordingly, Apotex will induce physicians and other healthcare professionals, resellers, pharmacies, and end users of Apotex's Infringing ANDA Products to directly infringe one or more claims of the '638 Patent. In addition, on information and belief, Apotex will encourage acts of direct infringement with knowledge of the '638 Patent and knowledge that it is encouraging infringement.

60. Apotex had actual and constructive notice of the ’638 Patent prior to filing Apotex’s ANDA and was aware that the filing of Apotex’s ANDA with the request for FDA approval prior to the expiration of the ’638 Patent would constitute an act of infringement of the ’638 Patent. Apotex had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, or importation of Apotex’s Infringing ANDA Products would not contribute to, or induce, the infringement of the ’638 Patent.

61. Apotex’s Paragraph IV Statement in the Notice Letter lacks any sufficient contention that Apotex’s Infringing ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the ’638 Patent.

62. In the Notice Letter, Apotex does not allege non-infringement of one or more claims of the ’638 Patent.

63. On information and belief, Apotex filed Apotex’s ANDA without adequate justification for asserting the ’638 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex’s Infringing ANDA Products. Apotex’s conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’638 Patent renders this case “exceptional” under 35 U.S.C. § 285.

64. Amgen will be irreparably harmed if Apotex is not enjoined from infringing, and from actively inducing and contributing to the infringement of the ’638 Patent. Amgen does not have an adequate remedy at law, and considering the balance of hardships between Amgen and Apotex, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

**COUNT 2**
**DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '638 PATENT**

65. Amgen states, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

66. Amgen's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

67. The '638 Patent includes claims that recite (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione; or a pharmaceutical composition or a single unit dosage form comprising (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione.

68. On information and belief, Apotex's Infringing ANDA Products contain (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione.

69. On information and belief, Apotex's Infringing ANDA Products are pharmaceutical compositions or single unit dosage forms containing (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione.

70. On information and belief, if Apotex's ANDA is approved, Apotex's Infringing ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, or will be imported into the United States, including the State of New Jersey, by or through Apotex and its affiliates. Apotex will therefore directly infringe one or more claims of the '638 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a).

71. On information and belief, Apotex knows that healthcare professionals or patients will use Apotex's Infringing ANDA Products in accordance with the labeling sought by Apotex's ANDA. On information and belief, the product label and product insert accompanying Apotex's

Infringing ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for OTEZLA®, attached as Exhibit A, and which, if followed, will infringe the '638 Patent. Apotex will therefore contribute to, or induce, the infringement of one or more claims of the '638 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c).

72. On information and belief, Apotex's infringing activity, including the commercial manufacture, use, offer for sale, sale, or importation of Apotex's Infringing ANDA Products complained of herein, will begin immediately after the FDA approves Apotex's ANDA. Any such conduct before the '638 Patent expires will directly infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '638 Patent under one or more of 35 U.S.C. § 271(a), (b), and (c).

73. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Amgen and Apotex concerning liability for the infringement of the '638 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

74. Amgen will be substantially and irreparably harmed by Apotex's infringing activities unless those activities are enjoined by this Court. Amgen has no adequate remedy at law.

75. This case is exceptional, and Amgen is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**COUNT 3**
**INFRINGEMENT OF THE '854 PATENT**

76. Amgen states, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

77. On information and belief, Apotex has submitted or caused the submission of Apotex's ANDA to FDA and continues to seek FDA approval of Apotex's ANDA.

78. Apotex has infringed the '854 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Apotex's ANDA with a Paragraph IV Certification and seeking FDA approval of Apotex's ANDA prior to the expiration of the '854 Patent.

79. The '854 Patent includes claims that recite methods of administering (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione.

80. On information and belief, Apotex's Infringing ANDA Products contain (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione.

81. Apotex's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Apotex's Infringing ANDA Products would directly infringe, or would actively induce or contribute to infringement of the '854 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c). Accordingly, unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will make, use, offer for sale, or sell Apotex's Infringing ANDA Products within the United States, or will import Apotex's Infringing ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '854 Patent. *See id.*

82. On information and belief, upon FDA approval of Apotex's ANDA, Apotex, through its own actions and through the actions of its agents and subsidiaries, will market and distribute Apotex's Infringing ANDA Products to resellers, pharmacies, hospitals and other clinics, healthcare professionals, and end users of Apotex's Infringing ANDA Products. On information and belief, Apotex will also knowingly and intentionally accompany Apotex's Infringing ANDA Products with a product label and product insert that will include instructions

for using or administering Apotex's Infringing ANDA Products. On information and belief, the product label and product insert accompanying Apotex's Infringing ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for OTEZLA®, attached as Exhibit A, and which, if followed, will infringe the '854 Patent. Accordingly, Apotex will induce physicians and other healthcare professionals, resellers, pharmacies, and end users of Apotex's Infringing ANDA Products to directly infringe one or more claims of the '854 Patent. In addition, on information and belief, Apotex will encourage acts of direct infringement with knowledge of the '854 Patent and knowledge that it is encouraging infringement.

83. Apotex had actual and constructive notice of the '854 Patent prior to filing Apotex's ANDA and was aware that the filing of Apotex's ANDA with the request for FDA approval prior to the expiration of the '854 Patent would constitute an act of infringement of the '854 Patent. Apotex had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, or importation of Apotex's Infringing ANDA Products would not contribute to, or induce, the infringement of the '854 Patent.

84. Apotex's Paragraph IV Statement in the Notice Letter lacks any sufficient contention that Apotex's Infringing ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '854 Patent.

85. In the Notice Letter, Apotex does not allege non-infringement of one or more claims of the '854 Patent.

86. On information and belief, Apotex filed Apotex's ANDA without adequate justification for asserting the '854 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's

Infringing ANDA Products. Apotex's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '854 Patent renders this case "exceptional" under 35 U.S.C. § 285.

87. Amgen will be irreparably harmed if Apotex is not enjoined from infringing, and from actively inducing and contributing to the infringement of the '854 Patent. Amgen does not have an adequate remedy at law, and considering the balance of hardships between Amgen and Apotex, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

**COUNT 4**
**DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '854 PATENT**

88. Amgen states, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

89. Amgen's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

90. The '854 Patent includes claims that recite methods of administering (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione.

91. On information and belief, Apotex's Infringing ANDA Products contain (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione.

92. On information and belief, if Apotex's ANDA is approved, Apotex's Infringing ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, or will be imported into the United States, including the State of New Jersey, by or through Apotex and its affiliates. Apotex will therefore directly infringe one or more claims of the '854 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a).

93. On information and belief, Apotex knows that healthcare professionals or patients will use Apotex's Infringing ANDA Products in accordance with the labeling sought by Apotex's ANDA. On information and belief, the product label and product insert accompanying Apotex's Infringing ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for OTEZLA®, attached as Exhibit A, and which, if followed, will infringe the '854 Patent. Apotex will therefore contribute to, or induce, the infringement of one or more claims of the '854 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c).

94. On information and belief, Apotex's infringing activity, including the commercial manufacture, use, offer for sale, sale, or importation of Apotex's Infringing ANDA Products complained of herein, will begin immediately after the FDA approves Apotex's ANDA. Any such conduct before the '854 Patent expires will directly infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '854 Patent under one or more of 35 U.S.C. § 271(a), (b), and (c).

95. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Amgen and Apotex concerning liability for the infringement of the '854 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

96. Amgen will be substantially and irreparably harmed by Apotex's infringing activities unless those activities are enjoined by this Court. Amgen has no adequate remedy at law.

97. This case is exceptional, and Amgen is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**COUNT 5**
**INFRINGEMENT OF THE ’541 PATENT**

98. Amgen states, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

99. On information and belief, Apotex has submitted or caused the submission of Apotex’s ANDA to FDA and continues to seek FDA approval of Apotex’s ANDA.

100. Apotex has infringed the ’541 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Apotex’s ANDA with a Paragraph IV Certification and seeking FDA approval of Apotex’s ANDA prior to the expiration of the ’541 Patent.

101. The ’541 Patent includes claims that recite methods of administering (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione.

102. Amgen’s cross-appeals regarding, *inter alia*, the rulings concerning the validity of claims 2, 19, and 21 of the ’541 Patent in Civil Action No. 18-11026 are currently pending as consolidated appeal No. 22-1147 at the Court of Appeals for the Federal Circuit. The remaining claims of the ’541 Patent were not adjudged to be invalid and are not pending on appeal.

103. On information and belief, Apotex’s Infringing ANDA Products contain (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione.

104. Apotex’s commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Apotex’s Infringing ANDA Products would directly infringe, or would actively induce or contribute to infringement of the ’541 Patent, including one or more claims of the ’541 Patent that are not pending on appeal, either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c). Accordingly, unless enjoined by this Court, upon FDA approval of Apotex’s ANDA, Apotex will make, use, offer for sale, or sell Apotex’s Infringing ANDA Products within the United States, or will import Apotex’s Infringing

ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '541 Patent, including one or more claims of the '541 Patent that are not pending on appeal. *See id.*

105. On information and belief, upon FDA approval of Apotex's ANDA, Apotex, through its own actions and through the actions of its agents and subsidiaries, will market and distribute Apotex's Infringing ANDA Products to resellers, pharmacies, hospitals and other clinics, healthcare professionals, and end users of Apotex's Infringing ANDA Products. On information and belief, Apotex will also knowingly and intentionally accompany Apotex's Infringing ANDA Products with a product label and product insert that will include instructions for using or administering Apotex's Infringing ANDA Products. On information and belief, the product label and product insert accompanying Apotex's Infringing ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for OTEZLA®, attached as Exhibit A, and which, if followed, will infringe the '541 Patent, including one or more claims of the '541 Patent that are not pending on appeal. Accordingly, Apotex will induce physicians and other healthcare professionals, resellers, pharmacies, and end users of Apotex's Infringing ANDA Products to directly infringe one or more claims of the '541 Patent, including one or more claims of the '541 Patent that are not pending on appeal. In addition, on information and belief, Apotex will encourage acts of direct infringement with knowledge of the '541 Patent and knowledge that it is encouraging infringement.

106. This case is exceptional, and Amgen is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

107. Amgen will be irreparably harmed if Apotex is not enjoined from infringing, and from actively inducing and contributing to the infringement of the '541 Patent. Amgen does not

have an adequate remedy at law, and considering the balance of hardships between Amgen and Apotex, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

**COUNT 6**
**DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '541 PATENT**

108. Amgen states, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

109. Amgen's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

110. The '541 Patent includes claims that recite methods of administering (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione.

111. On information and belief, Apotex's Infringing ANDA Products contain (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione.

112. On information and belief, if Apotex's ANDA is approved, Apotex's Infringing ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, or will be imported into the United States, including the State of New Jersey, by or through Apotex and its affiliates. Apotex will therefore directly infringe one or more claims of the '541 Patent either literally or under the doctrine of equivalents, including one or more claims of the '541 Patent that are not pending on appeal. *See* 35 U.S.C. § 271(a).

113. On information and belief, Apotex knows that healthcare professionals or patients will use Apotex's Infringing ANDA Products in accordance with the labeling sought by Apotex's ANDA. On information and belief, the product label and product insert accompanying Apotex's Infringing ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for OTEZLA®, attached as Exhibit A, and which,

if followed, will infringe the '541 Patent, including one or more claims of the '541 Patent that are not pending on appeal. Apotex will therefore contribute to, or induce, the infringement of one or more claims of the '541 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c).

114. On information and belief, Apotex's infringing activity, including the commercial manufacture, use, offer for sale, sale, or importation of Apotex's Infringing ANDA Products complained of herein, will begin immediately after the FDA approves Apotex's ANDA. Any such conduct before the '541 Patent expires will directly infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '541 Patent, including one or more claims of the '541 Patent that are not pending on appeal, under one or more of 35 U.S.C. § 271(a), (b), and (c).

115. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Amgen and Apotex concerning liability for the infringement of the '541 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

116. Amgen will be substantially and irreparably harmed by Apotex's infringing activities unless those activities are enjoined by this Court. Amgen has no adequate remedy at law.

117. This case is exceptional, and Amgen is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

## REQUEST FOR RELIEF

WHEREFORE, Amgen respectfully requests the following relief:

(a) The entry of a judgment, in favor of Amgen and against Apotex, that Apotex's submission of Apotex's ANDA to FDA seeking approval for the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of Apotex's

Infringing ANDA Products before the expiration of the Patents-in-Suit was an act of infringement of one or more claims of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A);

(b) The entry of a declaratory judgment, in favor of Amgen and against Apotex, declaring that Apotex's commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of Apotex's Infringing ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the Patents-in-Suit by Apotex under one or more of 35 U.S.C. § 271(a), (b), and (c);

(c) The entry of a judgment declaring that the Patents-in-Suit remain valid and enforceable;

(d) The entry of preliminary and permanent injunctions enjoining Apotex and its officers, directors, agents, servants, employees, parents, subsidiaries, affiliates, other related business entities, and all other persons and entities acting in concert, participation, or in privity with Apotex, and their successors or assigns, from commercially manufacturing, using, offering to sell, or selling Apotex's Infringing ANDA Products within the United States, or importing Apotex's Infringing ANDA Products into the United States, or inducing or contributing to such conduct, until the last of the expiration dates of the Patents-in-Suit, including any extensions or regulatory exclusivities, or any later expiration of exclusivity to which Amgen is or becomes entitled;

(e) The entry of a permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), enjoining Apotex and its officers, directors, agents, servants, employees, parents, subsidiaries, affiliates, other related business entities, and all other persons and entities acting in concert, participation, or in privity with Apotex, and their successors or assigns, from commercially manufacturing, using, offering to sell, or selling Apotex's Infringing ANDA Products within the

United States, or importing Apotex's Infringing ANDA Products into the United States, or inducing or contributing to such conduct, until the last of the expiration dates of the Patents-in-Suit, including any extensions or regulatory exclusivities, or any later expiration of exclusivity to which Amgen is or becomes entitled;

(f) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Apotex's ANDA shall be a date that is not earlier than the last of the expiration dates of the Patents-in-Suit, including any extensions or regulatory exclusivities, or any later expiration of exclusivity to which Amgen is or becomes entitled;

(g) A declaration under 28 U.S.C. § 2201 that if Apotex, its officers, directors, agents, servants, employees, representatives, attorneys, parents, subsidiaries, affiliates, other related business entities, or other persons or entities acting or attempting to act in concert, participation, or in privity with Apotex, or acting on Apotex's behalf, engage in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of Apotex's Infringing ANDA Products, then it will constitute an act of direct or indirect infringement of the Patents-in-Suit;

(h) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Apotex engages in the commercial manufacture, use, offer for sale, sale, or importation of Apotex's Infringing ANDA Products, or any product that infringes the Patents-in-Suit, or induces or contributes to such conduct, prior to the expiration of such patents, including any extensions or regulatory exclusivities;

(i) The entry of judgment declaring that Apotex's acts render this case an exceptional case and awarding Amgen its attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(j) An award to Amgen of its costs and expenses in this action; and

(k) Such other and further relief this Court deems just and proper.

Dated: June 14, 2022

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